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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,201	01/18/2002	Linus G. Fonkwe	4700-083 (04700.0467.4)	7237
30166	7590	12/17/2004	EXAMINER	
WOMBLE CARLYLE SANDRIDGE & RICE PLLC			KRISHNAN, GANAPATHY	
300 N. GREENE STREET			ART UNIT	
SUITE 1900			PAPER NUMBER	
GREENSBORO, NC 27401			1623	

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/051,201

Applicant(s)

FONKWE ET AL.

Examiner

Ganapathy Krishnan

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,5-8,10-12,14-23,26-32,35-45 and 62-105 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 62-69 is/are allowed.
- 6) ☒ Claim(s) 2,3,5-8,10-12,14-23,26-32,35-45 and 70-105 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

The amendment filed 9/24/2004 has been received, entered and carefully considered.

The following information provided in the amendment affects the instant application:

1. Claims 1, 4, 9, 13, 24, 25, 33, 34, 46-61 have been canceled.
2. New Claims 100-105 have been added.
3. Claims 2, 3, 5-8, 10-15, 17, 18, 26-32, 35-40 and 94-99 have been amended.
4. Remarks drawn to rejections under 103

Claims 2-3, 5-8, 10-12, 14-23, 26-32, 35-45 and 62-105 are pending in the case.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

The allowability of claims 62-93 and claims 16-23, 38-43 if rewritten in independent form including all of the limitations of the base claim and any intervening claims has been withdrawn and the following new rejections are made of record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 2, 3, 5-8, 10-12, 14-23, 26-32, 35-45, 70-75, 82-92, 94-104 are rejected under 35 U.S.C. 102(a) as being anticipated by Tanner et al (WO 01/03677) of record, newly cited.

Tanner et al teach a film forming composition (page 41, Table IV, formulation #16) wherein iota carrageenan is 7.5%, kappa carrageenan is 2.5%, pure cote B (modified starch, bulking agent) is 27.3%, water is 46.5% and glycerin (same as glycerol, a plasticizer; see also page 27, lines 6-13) is 15%. The kappa carrageenan is less than 100% by weight of the iota carrageenan. The ratio of modified starch (bulking agent) to the total of iota and kappa carrageenan is 2.73:1. Since this composition of Tanner et al has all the active agents in the percentage range as in instant claim 16 it is expected to have viscosity also in the range of 100cp to 1200cP, tensile strength in the range %N to 40N and extensibility at rupture of 20mm to 80mm. Example 1 (page 30, line 15 through page 31, line 2) teaches the formulation of the compositions by mixing appropriate quantities of each component in a blender, mixing with mixer blades to obtain a uniform dispersion and then extruded into ribbons (examples 2 and 3, pages 36-37). Tanner et al also teach making ribbons (wet and dry) using their formulations (page 36, lines 3-18). This teaching of Tanner et al is seen to meet the limitations of claims 2, 3, 5-8, 10-12, 14-23, 26-32, 35-45, 70-75, 82-92, 94-104.

Claim Rejections - 35 USC § 103

Claims 76-81, 93 and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanner (WO 01/03677) in combination with Gilleland et al (WO 01/91721), of record, newly cited.

Claim 76 is drawn to a method of film forming composition comprising adding a mixture of iota carrageenan in an amount of from about 1% to about 15% by weight, kappa carrageenan in an amount of less than 100% by weight of iota carrageenan, a bulking agent in a ratio of

Art Unit: 1623

bulking agent to total carrageenan of from about 1:1 to about 20:1, a plasticizer and water to an extruder and forming a uniform mixture. Dependent claims 77-82, 93 and 105 recite limitations drawn to mixing of different ingredients, extruding the mixture into film, ribbon sheet or tube, feeding the mixture into a rotary die machine, heating the mixture to about 85 to about 95°C before adding to the extruder.

Tanner et al teach a film forming composition (page 41, Table IV, formulation #16) wherein iota carrageenan is 7.5%, kappa carrageenan is 2.5%, pure cote B (modified starch, bulking agent) is 27.3%, water is 46.5% and glycerin (same as glycerol, a plasticizer; see also page 27, lines 6-13) is 15%. The kappa carrageenan is less than 100% by weight of the iota carrageenan. The ratio of modified starch (bulking agent) to the total of iota and kappa carrageenan is 2.73:1. Since this composition of Tanner et al has all the active agents in the percentage range as in instant claim 16 it is expected to have viscosity also in the range of 100cp to 1200cP, tensile strength in the range %N to 40N and extensibility at rupture of 20mm to 80mm. Example 1 (page 30, line 15 through page 31, line 2) teaches the formulation of the compositions by mixing appropriate quantities of each component in a blender, mixing with mixer blades to obtain a uniform dispersion and then extruded into ribbons (examples 2 and 3, pages 36-37). According to Tanner et al (page 28, lines 16-20) controlling the pH and hence the pH is important since high temperature and acidity causes the rapid breakdown of carrageenans. Tanner et al also teach making ribbons (wet and dry) using their formulations (page 36, lines 3-18). However, Tanner et al do not teach the order of mixing of the ingredients as instantly claimed.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a film forming composition using a mixture of iota and kappa carrageenan and starch/modified starch as a bulking agent since the ingredients and their functions are seen to be disclosed in the prior art. It is also well within the purview of one of ordinary skill in the art to adjust the ratio of the bulking agent and the kappa and iota carrageenans in order to optimize the characteristics of the films produced using the same and also reverse or change the order of mixing the ingredients of the composition. It has been held that merely reversing the order of steps in a multistep process is not a patentable modification absent unexpected or unobvious results. *Ex parte Rubin*, 128 U.S.P.Q. 440 (P.O.B.A 1959). *Cohn v. Comr. Patents*, 251 F. Supp. 437, 148 U.S.P.Q. 486 (D.C. 1966).

One of ordinary skill in the art would be motivated to do so since Gilleland's teaching shows that a mixture comprising 1:1 kappa and iota carrageenan, starch, sorbitol and water gives a film which is strong and easy to handle and seal and also has a manageable viscosity. Hence optimizing the ratio of the ingredients would give a composition that would be ideal for use in making capsule shells, ribbons and sheets.

Conclusion

1. Claims 2-3, 5-8, 10-12, 14-23, 26-32, 35-45 and 70-105 are rejected.
2. Claims 62-69 drawn to a method film forming composition comprising mixing the kappa and iota carrageenan and the bulking agent to form a dry mixture; mixing the plasticizer and water and heating it at a

Art Unit: 1623

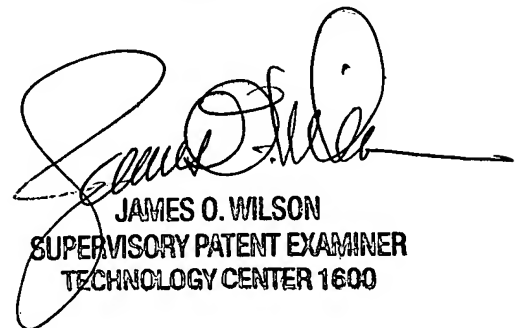
specified temperature to form a dispersion and then combining the two mixtures and heating again to a specified temperature to form a uniform mixture as instantly claimed is neither taught or suggested by the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK



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